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10/518,292	12/16/2004	Mark W. Cater	25029/101/101	7055
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			KASHNIKOW, ERIK	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/518,292 CATER ET AL. Office Action Summary Examiner Art Unit ERIK KASHNIKOW 1794 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 28 August 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-30 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-30 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 08/28/08

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. \_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

## Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 1-28 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- 3. In this instance the term non-aqueous, which was entered in the preliminary amendment is considered to be new matter. The cited phraseology clearly signifies a "negative" or "exclusionary" limitation for which the applicants have no support in the original disclosure. Negative limitations in a claim which do not appear in the specification as filed introduce new concepts and violate the description requirement of 35 USC 112, first paragraph, Ex Parte Grasselli, Suresh, and Miller, 231 USPQ 393. 394 (Bd. Pat. App. and Inter. 1983); 783 F. 2d 453.
- 4 The insertion of the above phraseology as described above positively excludes aqueous products, however, there is no support in the present specification for such exclusions. While the present specification is silent with respect to the use of aqueous products, is noted that as stated in MPEP 2173.05(i), the "mere absence of a positive recitation is not the basis for an exclusion."

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### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Akao et al. (US 5,492,741).
- 7. In regards to claims 1 and 2 Akao et al. teach an oxygen scavenging composition which can consist of glucose oxidase, glucose and a multitude of other chemicals. Akao et al. further teach that the oxygen scavenging system can further comprise a combination of these materials. In regards to these claims the glucose would act as the energy source and glucose oxidase would act as the enzyme system (column 30 line 62 column 31 line 22). Akao et al. further teach the inclusion of sodium bicarbonate and iron which would act as the non aqueous neutralizing agent (column 31 lines 15-17). Since sodium bicarbonate is a preferred neutralizing agent taught by Applicant's all the properties of the neutralizing agent taught in the instant claims are inherent. Since the materials used by Akao et al. are the same as those taught in the dependant and independent claims of the instant application they would be inherently dry. In regards to the last 2 lines of claim one, since Akao et al. teach the same materials as Applicant's all the limitations of the last two lines would also be inherent. It is also pointed out that

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given that Akao et al. disclose composition as presently claimed, it is clear that the composition would inherently enhance the shelf-life of a packaged product.

8. While it is recognized that the phrase "consisting essentially of" narrows the scope of the claims to the specified materials and those which do not materially affect the basic and novel characteristics of the claimed invention, absent a clear indication of what the basic and novel characteristics are, "consisting essentially of" is construed as equivalent to "comprising". Further, the burden is on the applicant to show that the additional ingredients in the prior art, i.e. iron, would in fact be excluded from the claims and that such ingredients would materially change the characteristics of the applicant's invention. See MPEP 2111.03.

## Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-4, 6-10, 12-19 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehotonen et al. (US 4,996,062) in view of Akao et al. (US 5,492,741) and dictionary.com used as evidentiary reference (http://dictionary.reference.com/browse/dextrose).
- Lehotonen et al. teach a foodstuff package which contains an oxygen scavenging system (column 3 lines 31-41).

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12. In regards to claims 1, 3-4, 6-10 and 27 Lehotonen et al. teach a package which contains foodstuff, as well as a mixture of the enzymes glucose oxidase and catalase, which is used to eliminate oxygen from the atmosphere (column 3 lines 31-41).

- In regards to claims 6 and 7 Lehotonen et al. also teach the use of glucose as a substrate in their oxygen scavenging system (column 5 lines 65-68).
- 14. In regards to claim 9, dextrose is one of two stereoisomers of glucose, and is the most common form of glucose, and therefore would be obvious to one of ordinary skill in the art at the time of the invention (See the definition of glucose as found on http://dictionary.reference.com/browse/dextrose.)
- 15. In regards to claims 12- 13 Lehotonen et al. teach that glucose oxidase be present in quantities of 10-1000 Units/kg (column 4 lines 4-5), and catalase in quantities of the same amount (Column 3 line 57-58) this meets the lower range of applicants claimed ranges.
- In regards to claim 24 Lehotonen et al. teach that the composition can be incorporated into the package prior to the addition of the food product (column 6 lines 49-52).
- 17. In regards to claims 25-28 Lehotonen et al. teach that the composition can also be embodied in a 3 dimensional form, when it is added to the actual food product (column 6 line 42-44), or sprayed onto the food product surface (column 6 lines 44-48).
- 18. In regards to claim 14 absent a showing of criticality with respect to the amount of glucose, it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the amount of glucose through routine experimentation in

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order to achieve an effective oxygen scavenger. It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

- 19. In regards to claims 15 and 17-19 it would have been obvious under the guidelines presented in the preceding paragraph to vary the amount of glucose and neutralizing agent present in order to achieve an effective oxygen scavenger.
- 20. As stated above Lehotonen et al. teach an enzyme system, however they are silent regarding the system comprising an oxidoreductase enzyme as well as a solid neutralizing agent.
- 21. In regards to claims 1 and 2 Akao et al. teach an oxygen scavenging composition which can consist of glucose oxidase, glucose and a multitude of other chemicals. Akao et al. further teach that the oxygen scavenging system can further comprise a combination of these materials. In regards to these claims the glucose would act as the energy source and glucose oxidase would act as the enzyme system (column 30 line 62 column 31 line 22). Akao et al. further teach the inclusion of sodium bicarbonate and iron which would act as the non aqueous neutralizing agent (column 31 lines 15-17). Since sodium bicarbonate is a preferred neutralizing agent taught by Applicant's all the properties of the neutralizing agent taught in the instant claims are inherent. Since the materials used by Akao et al. are the same as those taught in the dependant and independent claims of the instant application they would be inherently dry. In regards to the last 2 lines of claim one, since Akao et al. teach the same materials as Applicant's all the limitations of the last two lines would be intrinsically the same. It is also pointed

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out that given that Lehotonen et al. and Akao et al. disclose composition as presently claimed, it is clear that the composition would inherently enhance the shelf-life of a packaged product.

- 22. In regards to claim 29 Akao et al. teach that sodium bicarbonate is included in its oxygen scavenging system however are silent regarding it being in powder form, however one of ordinary skill in the art at the time of the invention would be aware that sodium bicarbonate is a white solid, and it would be obvious to one of ordinary skill in the art at the time of the invention to include this white solid in powder form so as to be able to include the sodium bicarbonate easily into the package.
- 23. In regards to claim 30 while Lehotonen et al. state that the powder form can be prepared with an inert carrier material, it would be obvious to one of ordinary skill in the art that the inclusion of the neutralizing agent of Akao et al. into the package would eliminate the need for the carrier material, as the sodium bicarbonate would be able to act as a carrier material.
- 24. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the package containing an oxygen scavenging system of Lehotonen et al. with the oxygen scavenging system of Akao et al. because the package of Lehotonen et al. which offers the inhibition of growth of aerobic spoilage organisms, would benefit from the ability to protect food that is degrade by oxygen (column 39 lines 27-35).

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25. Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Lehotonen et al. (US 4,996,062) in view of Akao et al. (US 5,492,741) and Stougaard et

al. (US 6,251,626).

26. As stated above Lehotonen et al. and Akao et al. teach a composition for use as

an oxygen scavenging system for food. However both Lehotonen et al. and Akao et al.

are silent regarding the use of hexose oxidase.

27. Stougaard et al. teach that hexose oxidase is an enzyme that in the presence of

oxygen can capable of oxidizing dextrose and a multitude of other reducing sugars

(column 1 lines 19-20).

28. It would be obvious to one of ordinary skill in the art at the time of the invention to

use this in the inventions of Lehotonen et al. and Akao et al. because this enzyme can

utilize a broader range of substrates and therefore make the claimed invention more

flexible (column 1 lines 27-28).

29. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Lehotonen et al. (US 4,996,062) in view of Akao et al. (US 5,492,741) and Ernst (US

5.284.871).

30. As stated above Lehotonen et al. and Akao et al. teach a composition for use as

an oxygen scavenging system for food. However both Lehotonen et al. and Akao et al.

are silent regarding the use of water permeable enclosures for the composition.

Lehotonen

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31. Ernst teaches storing an oxygen scavenging system in a water permeable container enclosed with the product, including pouches (column 8 line 67 to column 9 line 9). It would also be obvious to one of ordinary skill in the art that a pouch and enclosed pouch and a sachet are all different design choices for a pouch.

32. It would be obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Lehotonen et al. and Akao et al. with the invention of Ernst because the invention of Ernst further protects foods by preventing the release of radicals into the food (column 9 lines 37+).

## Response to Arguments

- 33. Applicant's arguments, see arguments, filed 08/20/08, with respect to 35 U.S.C.
  112 2<sup>nd</sup> paragraph rejections have been fully considered and are persuasive. The 112
  2<sup>nd</sup> paragraph rejection of claim 27 has been withdrawn.
- 34. Applicant's arguments, see arguments, filed 08/28/2008, with respect to the rejection(s) of claim(s) 3,4, 6-10, 12-19 and 24-28 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lehotonen et al (US 4,996,062) in view of Akao et al (5,492,741).
- 35. In regards to Applicant's arguments concerning the 35 U.S.C. 112 1<sup>st</sup> paragraph rejection. Examiner acknowledges that Applicant has examples which show embodiments wherein the system is non aqueous however it is noted by Examiner that the mere absence of a positive limitation is not basis for a negative limitation claim.

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(MPEP 2173.05(i)). It is agreed that lack of literal basis alone may not be sufficient to establish a case for lack of descriptive support. However, in the present case, there is nothing in the present specification that supports the recitation of "non-aqueous neutralizing agent" as presently claimed. Applicants point to the abstract and page 7 of the present specification that list what the instant invention includes and state that based on the amounts, aqueous usage is excluded. However, these amounts refer to the final composition not the neutralizing agent itself. It is agreed that the final composition is dry, however, this does not provide support regarding the types of ingredients that were used to make the composition or exclude the use of aqueous components to make the final composition. Applicants also argue that the specification discloses that the composition binds oxygen when exposed to moisture. However, again, this refers to the final composition and not the neutralizing agent itself.

36. In regards to Applicant's arguments concerning the Akao rejection, Examiner points out that claim 1 and 2 do not require that the enzyme system is activated by moisture of the packaged product, that the system scavenges oxygen from the package headspace or performs an enzymatic oxidase and/or catalase reaction. Therefore the fact that the invention of Akao does not mention some of these properties, and that the invention of Akao is present in an inner layer and not within the package itself does not preclude the reference from being used as a 102(b) reference. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the enzyme system is activated by moisture of the packaged product, that the system scavenges

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oxygen from the package headspace or performs an enzymatic oxidase and/or catalase reaction) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In regards to Applicant's arguments regarding the fact that Akao does not expressly disclose that sodium bicarbonate is combined with glucose and glucose oxidase Examiner agrees, however, the examiner points out that Akao does explicitly teach oxygen enzyme systems of more than one component (column 31 lines 7-10) and as glucose, glucose oxidase and sodium bicarbonate are include in the list of possible components Akao et al. have taught the claimed invention. In regards to the requirement that the claimed invention extends the shelf life of the material and prevents any consumer noticeable degradation, Examiner asserts that the Akao reference is meeting these limitations, by protecting the package from degradation the oxygen scavenging system is extending the shelf life of the package and as an extension thereof the article within the package. Examiner also points out that while Applicants argue that Akao et al. would not attain the enzymatic consumption and stable pH required in the claim. Applicants have provided no evidence to support this position. In response to Applicants argument that a polyolefin is the main ingredient in the layer containing the oxygen scavenging system, Examiner points out that the polyolefin is not a part of the organic oxygen scavenging system, and is instead the layer which contains the oxygen scavenging system.

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37. In regards to Applicant's arguments regarding the Akao and Lehotonen 103 rejection. Examiner has agreed and replaced the rejection with a rejection which has Lehotonen in view of Akao, and in the view of expedited prosecution Examiner will respond to the arguments regarding the old rejection that could still apply to the new rejection. Specifically regarding the fact that Lehotonen is silent regarding solid buffering agents, examiner points out that this is why the Akao reference is brought in. and as stated above Akao teaches the use of sodium bicarbonate, a solid neutralizing agent. In regards to arguments regarding consisting essentially thereof, while it is recognized that the phrase "consisting essentially of" narrows the scope of the claims to the specified materials and those which do not materially affect the basic and novel characteristics of the claimed invention, absent a clear indication of what the basic and novel characteristics are, "consisting essentially of" is construed as equivalent to "comprising". Further, the burden is on the applicant to show that the additional ingredients in the prior art, i.e. iron, would in fact be excluded from the claims and that such ingredients would materially change the characteristics of the applicant's invention, See MPEP 2111.03. Examiner also points out that in the rejections current format the only portion of the Akao reference being used are the oxidoreductase and the solid neutralizing agent. In regards to Applicant's argument that the sodium bicarbonate in Akao is not expressly stated as a neutralizing agent. Examiner points out that it is present, and as it is the same material as required by Applicant's it would still perform the neutralizing functions required in the instant invention. Examiner points out that an amount not to exceed 30% fits within Applicant's range. In regards to Applicant's

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arguments regarding claims 26-28, the rearranging of the rejection was undertaken to meet the limitations of these claims.

- 38. In response to Applicant's arguments that none of the references meet new claim 30, Examiner points to the rejection of claim 30 using Lehotonen in view of Akao as teaching an organic oxygen scavenging system which consists of an enzyme system, a suitable enzyme source, and the neutralizing agent of Akao et al. replacing the carrier material of Lehotonen.
- 39. In regards to the arguments concerning the Stougaard and Ernst references note that while they do not disclose <u>all</u> the features of the present claimed invention, they are used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention. If the secondary reference contained all the features of the present claimed invention, it would be identical to the present claimed invention, and there would be no need for secondary references.

#### Conclusion

40. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Strobel et al. (US 5,766,473) and Hitzman (US 4,414,334) teach oxygen scavenging systems but are silent regarding a non agueous buffer agent.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIK KASHNIKOW whose telephone number is (571)270-3475. The examiner can normally be reached on Monday-Friday 7:30-5:00PM EST (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Erik Kashnikow Examiner Art Unit 1794

/Callie E. Shosho/ Supervisory Patent Examiner, Art Unit 1794 Art Unit: 1794